

## **REMARKS/ARGUMENTS**

Claims 1-13 were pending in the instant application. In order to expedite prosecution, Applicants have amended claims 1-4, 6-8, and 11 and have cancelled claims 5, 9-10, and 12-13 to more particularly point out and distinctly claim that which Applicants consider to be their invention. The amended claims 1-4, 6-8, and 11 are fully supported in the specification as originally filed. Support for amended claim 1 can be found on page 3, lines 31-37 of the specification of publication WO2005/058371 and in cancelled claims 5 and 10. Therefore, the amendments to claims 1-4, 6-8, and 11 do not add new matter. Applicants respectfully request that the amendments be entered.

Upon entry of the above-made amendments claims 1-4, 6-8, and 11 will be pending in the current application.

The following remarks, in conjunction with the above amendment, are believed to be fully responsive to the Office Action.

### **1. Information Disclosure Statement.**

Applicants note that copies of the foreign patent documents were inadvertently omitted from the IDS filed 14 June 2006. Copies are now provided with the exception of WO 00/61194, which is in German. In its place, Applicants have added US Patent 6,630,570 to the IDS, as it is the US equivalent of WO 00/61194 and is in English.

### **2. Claim Rejections: 35 USC §101.**

Claim 13 stands rejected in this regard, but Applicants had already cancelled claim 13. The objection is therefore moot.

### **3. Claim Rejections: 35 USC §112.**

Claims 1-13 stand rejected in this regard. Since claim 13 had already been cancelled, the rejection thus is to be directed at Claims 1-12 now.

Claim 1 has been amended to include the elements of previous claims 10 and 5. Previous claims 5, 9, 10 and 12 have been cancelled. Amended claim 1 is now limited to a method of optical imaging of oesophageal cancer and Barrett's oesophagus of an animate subject. The claim is no longer to optical imaging contrast agents *per se*. Hence, it can no longer be argued that the claim pertains to compounds defined only by their function. In addition, the claim scope has been limited to the five biological targets of previous claim 5.

Applicants contend that the specification provides sufficient information for the person skilled in the art to reproduce the method of amended claim 1. The specification provides suitable optical reporters; a description of suitable optical imaging techniques (page 15 lines 1-18); plus a description of targeting molecules and methods of labelling them with optical reporters. The person skilled in the art can either use the contrast agents described in the specification, or generate new ones. Applicants suggest that the claim scope for such an optical imaging method claim should not be limited by the possible future advent of new targeting molecules. If a person skilled in the art has available a compound with affinity for E-cadherin, CD44, P62/c-myc (HGF receptor), p53 or EGFR/erB-2can, then labelling such a compound with an optical reporter is taught by the present specification.

The revised claims are therefore believed to comply with 35 USC §112, and Applicants contend that this rejection should be withdrawn.

#### **4. Claim Rejections: 35 USC §102.**

Previous claims 1-4, 6-9 and 12 stand rejected as lacking novelty over Weissleder to US 2003/0044353 A (“Weissleder”).

Applicants note that no objection was made *versus* previous claim 10. Since that forms the basis for amended claim 1 (together with also the features of previous claim 5), Applicants contend that revised claim 1 is novel over Weissleder. By definition, dependant claims 2-4, 6-8 and 11 are also believed novel over Weissleder.

Previous claims 1, 3, 5 and 7-13 also stand rejected as lacking novelty over Ito to US 5,968,479 (“Ito”). Applicants acknowledge that Ito mentions oesophageal cancer (Column 9, line 24). The “diagnostic markers” of Ito comprise:

- (a) detection systems;
- (b) fluorescent functional group.

Ito describes (Column 9 lines 10-28) that the detection system is an antibody. Ito recites (*ibid* lines 19-22):

“...anti-tumor antibodies relating to stomach which specially react with CEA, AFA, CA19-9, NSE DU-PAN-2, CA50, SPan-1, CA72-4, CA125, HCG, p53, STN (sialyl Tn antigen), c-erbB-2 proteins and the like...”

Thus, the only disclosure of Ito in relation to page 53 is in relation to the stomach, not the oesophagus. Example 12 of Ito refers to anti-EMA antibodies, where EMA is Epithelial Membrane Antigen [see Example 7(a) of Ito]. Ito therefore does not disclose the optical imaging method of amended claim 1. Applicants stress that currently amended claim 1 teaches optical imaging of the oesophagus using contrast agents with affinity for certain defined biological targets. Ito provides no teaching on these targets in connection with the imaging of either oesophagus cancer or Barrett’s oesophagus. Since Ito does not teach all the essential features of revised claim 1, that claim is believed novel over Ito. By definition, dependant claims 2-4, 6-8 and 11 are also believed novel over Ito. The novelty objections based on Ito should therefore be withdrawn.

Previous claims 1-3, 6-9 and 12 also stand rejected as lacking novelty over Klaveness (US 6,610,269). The Examiner relied on the disclosure in Klaveness of compounds suitable for binding to the VEGF receptor. Applicants refer to currently amended claim 1. Klaveness is believed silent on the optical imaging of oesophagus cancer or Barrett’s oesophagus. In addition, VEGF is not one of the biological targets within the scope of amended claim 1.

Appl. No. 10/582,679  
Amdt. Dated March 5, 2009  
Reply to Office Action dated: December 9, 2008

Hence, revised claim 1 is believed novel over Klaveness. By definition, defendant claims 2-4, 6-8 and 11 are also believed novel over Klaveness.

**5. Double Patenting.**

Claims 1-12 stand provisionally rejected in this regard over co-pending US applications 10/573,604; 10/573,606; 10/582,680; 10/582,842 and 10/582,893.

Applicants note that this is a provisional obviousness-type double patenting rejection, since the conflicting claims are as yet still pending. Applicants contend that the currently amended claims are now patentably distinct, and that therefore this provisional rejection should be withdrawn.

**CONCLUSION**

In view of the amendments and remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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